IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: BARENHOLZ=9A

In re Application of:

Yechezkel Barenholz et al

Appln. No.: 10/551,649

I.A. Filed: 03/03/2004
371(c) 09/29/2005

For: STABLE LIPSOMES OR
MICELLES COMPSISING...

Conf. No.: 5688

Art Unit: 4121

Examiner: Isaac SHOMER

Washington, D.C.

May 18, 2009

REPLY TO RESTRICTION AND ELECTION REQUIREMENTS

Honorable Commissioner for Patents U.S. Patent and Trademark Office Customer Service Window, Mail Stop Amendment Randolph Building, 401 Dulany Street Alexandria, VA 22314

Sir:

Applicants are in receipt of the Office Action mailed March 24, 2009, in the nature of restriction and election of species requirements based on purported lack of unity of invention. Attached is a petition for one month's extension of time, along with the extension fee.

First, restriction has been required between what the PTO deems as being five (5) separate inventions. As applicants are required to make an election even though the requirement is traversed, applicants hereby respectfully and Appln. No. 10/551,649 Reply dated May 18, 2009 Reply to Office Action of March 24, 2009

provisionally elect Group I with traverse and without prejudice.

Applicants especially and particularly traverse with respect to Group IV which is directed to a pharmaceutical composition comprising the lipid assembly of Group I.

Applicants do not see how this can be classified as a separate and patentably distinct invention from the invention of Group I. Even if the requirement is maintained as to the other groups, applicants request that Group IV, presently comprising only claim 26, be rejoined.

More generally, applicants believe that unity of invention exists throughout the claims of the present application. As to Groups I-III, most of the claims in each group are the same, namely claims 1-8, 10, 11 and 13. The generic nature of these claims inherently serve to define the same or corresponding special technical features. Indeed, even if none of the generic claims were patentable (and certainly this has not been established), there would still be common subject matter defined by a narrower generic claims encompassing all of Groups I, II and III.

Applicants moreover respectfully note that any applicant has the right to claim his or her invention as broadly as the prior art and Section 112 permit. When the PTO requires restriction between or among groups which share the

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same claims, the PTO is in effect rejecting such claims, but without any statutory authority to do so, without any basis, and without any stated rejections. Such action is prohibited by a line of cases going back to the 1970's including In re Weber et al, 198 USPQ 328, 331 (CCPA 1978).

The restriction requirement should be withdrawn and such is respectfully requested.

In addition to the restriction requirement, the PTO has also made three requirements for elections of species.

Again, as applications must make the elections even though the requirements are traversed, applicants hereby respectfully and provisionally elect as set forth below, in each case with traverse and without prejudice.

Biologically active lipid: CERAMIDE Lipopolymer: POLYETHYLENE GLYCOL(PEG) Phospholipid: PHOSPHATIDYLCHOLINE

The claims which read on these elected species are claim 1-7, 10, 11, 13, 14, 16, 26 and 54.

The requirements are respectfully traversed for the same reasons as indicated above, i.e. the generic claims themselves provide unity of invention because they encompass and therefore are linked to form a single general inventive concept under PCT Rule 13.1, because the generic nature of the

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claims encompass the same or corresponding special technical features. Again, any applicant is entitled to one or more generic claims unless those claims are validly rejected.

Applicants understand that even if the election of species requirement were to be maintained, the applicants would still be entitled to consideration of claims to additional species which fall within the scope of any such allowed generic claim, as confirmed by the bottom paragraph on page 7 of the Office Action and again in the third paragraph on page 9 of the Office Action.

Applicants now respectfully await the results of a first examination on the merits.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C. Attorneys for Applicants

Bv

Sheridan Neimark

Registration No. 20,520

SN:jnj

Telephone No.: (202) 628-5197 Facsimile No.: (202) 737-3528

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